CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

40230

CORRESPONDENCE

ANDA 40-230

Lannett Company Inc.
Attention: Vlad Mikijanic
9000 State Road
Philadelphia PA 19136

JUN 23 1997

Dear Sir:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505 (j) of the Federal Food, Drug and Cosmetic Act for Dicyclomine Hydrochloride USP, 20 mg.

1. The Division of Bioequivalence has completed its review and has no further questions at this time.

2. The dissolution testing will need to be incorporated into your stability and quality control programs as specified in USP 23.

Please note that the bioequivalency comments expressed in this letter are preliminary. The above bioequivalency comments may be revised after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling or other scientific or regulatory issues. A revised determination may require additional information and/or studies, or may conclude that the proposed formulation is not approvable.

Sincerely yours,

/S/

for Nicholas Fleischer, Ph.D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 40-230

Lannett Company Inc.
Attention: Vlad Mikijanic
9000 State Road
Philadelphia, PA 19136

Dear Sir:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Dicyclomine Hydrochloride Tablets USP, 20 mg

DATE OF APPLICATION: December 19, 1996

DATE OF RECEIPT: December 20, 1996

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Kassandra Sherrod
Project Manager
(301) 594-1300

Sincerely yours,

/S/ 2/3/97

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Lannett LANNETT COMPANY INC.
9000 STATE ROAD, PHILADELPHIA, PA 19136

NEW CORRESP
N/C

January 19, 1999

Office of Generic Drugs
CDER/FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ANDA COMMITMENT

Re: ANDA 40-230, Dicyclomine Hydrochloride Tablets USP, 20 mg

Dear Sir or Madam,

It has recently been brought to our attention by Dr. Karen Bernard, Reviewing Chemist for the Office of Generic Drugs, that our proposed specification of % RSD NMT % for in-process blend uniformity testing is not acceptable. Therefore, we commit to change the in-process blend uniformity specification to % RSD NMT % prior to the above-referenced application being marketed.

If you have any questions or comments regarding our commitment or our pending Abbreviated New Drug Application for Dicyclomine Hydrochloride Tablets USP, 20 mg, please do not hesitate to contact me directly.

Thank you.

Sincerely,
For Lannett Company Inc.

Vlad Mikijanic
Vice President
Technical Affairs

RECEIVED
JAN 21 1999

TELE: 215-333-9000 • 1-800-325-9994 • FAX: 215-333-9004 • LannCo@worldnet.att.net

Lannett LANNETT COMPANY INC.
9000 STATE ROAD, PHILADELPHIA, PA 19136

December 22, 1998

Office of Generic Drugs
CDER/FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

FACSIMILE AMENDMENT

Re: ANDA 40-230, Dicyclomine Hydrochloride Tablets USP, 20 mg; Minor Amendment Response

Dear Sir or Madam,

Lannett Company is in receipt of your recent facsimile correspondence, entitled Facsimile Amendment, dated November 30, 1998. In accordance with 21 CFR 314.120(a)(1), we respectfully amend our ANDA with responses to your questions, along with pertinent attachments. In addition, we have also submitted a certified true field copy of this Amendment to the Philadelphia District Office as required by 21 CFR 314.60.

If you have any questions or comments concerning the information in this submission, please do not hesitate to contact me.

Thank you.

Sincerely,
For Lannett Company Inc.

Vlad Mikijanic
Vice-President
Technical Affairs

TELE: 215-333-9000 • 1-800-325-9994 • FAX: 215-333-9004 • LannCo@worldnet.att.net

Lannett LANNETT COMPANY INC.
9000 STATE ROAD, PHILADELPHIA, PA 19136

October 16, 1998

Ms. Debra L. Pagano
Philadelphia District
Pre-Approval Manager
Food & Drug Administration
Room 900, U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106-2973

FACSIMILE AMENDMENT

Re: ANDA 40-230, Dicyclomine Hydrochloride Tablets USP, 20 mg

Dear Ms. Pagano,

Enclosed please find a copy of our Amendment to the above-referenced application that was submitted to the Office of Generic Drugs yesterday, October 15, 1998. This Amendment is submitted pursuant to 21 CFR 314.120 in response to a facsimile deficiency letter that we received on September 15, 1998.

If you have any questions, please do not hesitate to contact me.

Thank you.

Sincerely,
For Lannett Company Inc.

Susan Williamson

Susan Williamson
Regulatory Affairs Associate

TELE: 215-333-9000 • 1-800-325-9994 • FAX: 215-333-9004 • LannCo@worldnet.att.net

Lannett LANNETT COMPANY INC.
9000 STATE ROAD, PHILADELPHIA, PA 19136

October 15, 1998

Office of Generic Drugs
CDER/FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

FACSIMILE AMENDMENT

Re: ANDA 40-230, Dicyclomine Hydrochloride Tablets USP, 20 mg; Minor Amendment Response

Dear Sir or Madam,

Lannett Company is in receipt of your recent facsimile correspondence, entitled Minor Amendment, dated September 15, 1998. In accordance with 21 CFR 314.120(a)(1), we respectfully amend our ANDA with responses to your questions, along with pertinent attachments. In addition, we have also submitted a certified true field copy of this Amendment to the Philadelphia District Office as required by 21 CFR 314.60.

If you have any questions or comments concerning the information in this submission, please do not hesitate to contact me.

Thank you.

Sincerely,
For Lannett Company Inc.

Vlad Mikijanic
Vice-President
Technical Affairs

TELE: 215-333-9000 • 1-800-325-9994 • FAX: 215-333-9004 • LannCo@worldnet.att.net

Lannett LANNETT COMPANY INC.
9000 STATE ROAD, PHILADELPHIA, PA 19136

January 9, 1998

NDA [illegible]MENT

N/AC

Office of Generic Drugs
CDER/FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

MAJOR AMENDMENT
TO ANDA

Re: ANDA 40-230, Dicyclomine Hydrochloride Tablets USP, 20 mg

Dear Sir or Madam,

Lannett Company is in receipt of your correspondence, dated April 24, 1997, which details deficiencies with our Abbreviated New Drug Application for Dicyclomine Hydrochloride Tablets USP, 20 mg which was submitted to your office on December 19, 1996.

In accordance with 21 CFR 314.120(a)(1), we respectfully amend our ANDA. Presented here are our responses to the deficiencies, as well as a side-by-side comparison of the revised package insert labeling. We have also submitted a certified true field copy to the Philadelphia District Office as required by 21 CFR 314.60(c).

If you have any questions or comments concerning the information contained within this submission, please do not hesitate to contact me.

Thank you.

Sincerely,
for Lannett Company Inc.

Vlad Mikijanic
Vice-President
Technical Affairs

RECEIVED
JAN 12 1998
GENERIC DRUGS

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Lannett LANNETT COMPANY INC.
9000 STATE ROAD, PHILADELPHIA, PA 19136

May 1, 1997

NEW

Ms. Lucy Sanchez
Division of Bioequivalence
OGD/CDER/FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

MINOR AMENDMENT
TO ANDA SUBMISSION

Re: ANDA 40-230, Dicyclomine Hydrochloride Tablets USP, 20 mg

Dear Ms. Sanchez,

This letter is in response to our telephone conversation on Friday, April 25, 1997. You requested that I provide you with the following information: 1) clarification of the dissolution data charts and tables (dissolution time points do not correspond on the charts and tables and the table contains mean and relative standard deviation information but the charts do not), 2) provide your office with the dissolution method for Dicyclomine Hydrochloride Tablets USP, 20 mg, and 3) state the batch size and the Actual Final Yield of the bio-batch, lot #61282001.

The dissolution time point of 60 minutes reported on the submitted tables is incorrect. The correct dissolution time point is 45 minutes. The dissolution limit is NLT % (Q) in 45 minutes. The tables do not contain information at 0 minutes because all the values are 0. This was omitted from the table for aesthetic reasons. All tables have been corrected from 60 minutes to 45 minutes. The dissolution charts have been revised slightly to include a table at the bottom of each page to provide the results for each tablet at each time point. The reader is directed to the corresponding tables for Standard Relative Deviation data. In addition, two additional charts and tables are included. These are the Dissolution Mean Profile for tablets 1-6 and for tablets 1-12, Lannett Lot #61282001 versus Bentyl, lot #4786EL, and the corresponding tables. Please refer to Attachment I for the above-mentioned information.

Attachment II contains the Finished Product Test Method for Dicyclomine Hydrochloride Tablets USP, 20 mg, Test Method #1282-002. The dissolution method is described in detail starting with page 6 of 8 of the analytical method.

The theoretical yield of lot #61282001, the submission and bio-batch lot, is tablets. The Actual Final Yield was tablets or %. Please be aware that the theoretical yield of tablets represents a full-size production lot.

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We respectfully submit the above information for your review and approval. If you have any questions or require any additional information, please do not hesitate to contact me.

Thank you.

Sincerely,
for Lannett Company Inc.

Vlad Mikijanic
VP, Technical Affairs

Lannett LANNETT COMPANY INC.
9000 STATE ROAD, PHILADELPHIA, PA 19136

April 22, 1997

Ms. Lucy Sanchez
Division of Bioequivalency
Office of Generic Drugs
CDER/FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NEW CORRESP BIOAVAILABILITY
NC/Bio Per Lucy

RE: ANDA 40-230, Dicyclomine Hydrochloride Tablets USP, 20 mg

Dear Ms. Sanchez,

Per your telephone conversation today with Vlad Mikijanic, enclosed please find a floppy disk containing our bioequivalence study information.

If you have any questions or comments, do not hesitate to contact Vlad Mikijanic or myself. Thank you.

Sincerely,
for Lannett Company Inc.

Susan Williamson
Regulatory Affairs Associate

RECEIVED
APR 2 5 1997
GENERIC DRUGS

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Lannett

LANNETT COMPANY INC.
9000 STATE ROAD, PHILADELPHIA, PA 19136

December 19, 1996

Office of Generic Drugs
CDER/FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

RE: ANDA Submission for Dicyclomine Hydrochloride Tablets USP, 20 mg

Dear Sir,

Lannett Company respectfully submits, pursuant to 21 CFR 314.94, an Abbreviated New Drug Application for Dicyclomine Hydrochloride Tablets USP, 20 mg. Lannett Company's Dicyclomine Hydrochloride Tablets USP, 20 mg are bioequivalent to the listed drug, Bentyl, NDA #07-409, manufactured by Marion Merrell Dow.

We are submitting both an archival copy and a review copy. The archival copy consists of four volumes bound in blue folders. The review copy consists of three volumes bound in orange folders and two volumes bound in red folders for a total of five volumes.

For more information regarding the organization of this ANDA, please refer to page 1 "Executive Summary".

Please direct any questions or comments regarding this ANDA to my attention at the address listed above or you may contact me by telephone at 215-333-9000.

Thank you for your prompt handling of this submission.

Sincerely,
for Lannett Company Inc.

Vlad Mikijanic
Vice-President
Technical Affairs

RECEIVED DEC 20 1996 GENERIC DRUGS

RECEIVED 20 GENERIC DRUGS

TELE: 215-333-9000 • 1-800-325-9994 • FAX: 215-333-9004 • LannCo@worldnet.att.net